STD Clinical Standards and Monitoring Guidelines

Adopted March 2004

Prepared by
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MINIMUM STANDARDS FOR STD CLINICAL SERVICES

These standards are based on the 2001 CDC Program Operations Guidelines for STD Prevention, Medical and Laboratory Services; the essential functions contained in the Comprehensive STD Prevention Systems Program announcement; the 1991 CDC STD Clinical Practice Guidelines; the 1997 TDH Client Services Standard for Public Health and Community clinics.

A. ACCESSIBILITY/CLINIC ENVIRONMENT

1. The clinic facility is physically accessible in accordance with the Americans with Disabilities Act.

2. The clinic is located so that it is readily accessible through public and private transportation from residential areas.

3. Clinic hours and staffing are sufficient to accommodate patients, with minimal patients turned away. (A minimum of 90% of clients seeking STD services will be seen the same day they seek services.

4. A system to document number of patients not seen “same day seeking services” is in place.

5. A system to periodically assess clinic user (or patient) satisfaction with services is in place and information obtained is used to improve services.

6. No patient is denied care for lack of money. Medical services should be at no charge, minimal, or based on a sliding scale.

7. Fees are not assessed for examining persons referred by a disease intervention specialist.

8. Examination rooms are clean and private and have adequate equipment and supplies for physical examinations and specimen collection for both male and female patients.

9. The number of examination rooms is adequate to accommodate the number of clinicians (at least one room per clinician) and to serve patients promptly during the normal working day.

B. RANGE OF SERVICES

1. At a minimum, clinic has the capability to accurately diagnose and treat bacterial STDs (syphilis, gonorrhea, chlamydia, chancroid).

2. Confidential counseling and testing for HIV are offered in accordance with *TDH HIV/STD Guidelines, Guidelines for HIV Testing in STD Clinics*, at the time of the STD visit so that patients do not have to visit separate clinics or make return visits.

3. Clinic has the capacity to distribute medications for diseases diagnosed in the clinic. At a minimum, medications must be available for locally prevalent STDs, with prescriptions available for diagnosed diseases not prevalent in the community.

4. Clinic provides condoms and counseling on primary prevention to all patients.

5. If clinic provides Pap smears, specific protocols for follow-up of abnormal results that include guidelines for colposcopy referral are in place.

6. If clinic provides pregnancy tests, specific protocols for follow-up and referral of positive tests are in place.

7. Confidential counseling and testing for STDs, including HIV, are not denied because a patient refuses other STD services.

HIV testing is available on site for patients requesting the service or at community sites convenient to patients. *TDH HIV/STD Guidelines, Guidelines for HIV Testing in STD Clinics* states that confidential testing is the preferred method.

Written policy and procedures are in place for the referral of patients for HIV early intervention services (e.g., continuing medical evaluation, tuberculosis and immune system testing, treatment, penicillin desensitization, and support group counseling).

When not offered on site, the mechanisms for referral are established for relevant health services (e.g., family planning, prenatal, adult immunizations, drug counseling) and a method to confirm appointments is in place.

C. PATIENT CONSIDERATIONS

1. Patient confidentiality must be maintained. Confidentiality is promoted by using a system other than names when calling patients from waiting areas.

2. Clinic personnel are courteous and respectful of patients.

3. An adequate portion of the clinic staff has bilingual fluency that facilitates services to those patients who do not speak English.

4. An interpreter is available for deaf and hard of hearing patients.

5. Clinic assesses the need for physical security during clinic sessions and has security protocols in place.

D. REGISTRATION PROCESS – CONFIDENTIALITY & PROCEDURE

1. Registration information is obtained in a confidential manner.

2. Positive HIV test results are not to be given over the telephone.

3. Telephone reports of STD test results strictly follow clinic procedures to ensure confidentiality.

4. Clinic has systems in place to assess and modify patient visits to assure minimal waiting.

5. The “expected-in” file is checked for every person at every visit as part of the registration process. (“expected-in” is a record file of pending follow-up or priority examinations for disease intervention for the following: persons with reactive test results and untreated from the clinic or other facilities; sex partners or cluster suspects of diagnosed patients; and persons who need special repeat testing.)

6. Priority patients (DIS referrals, follow-up visits) are given preferential service.

E. CLINIC FLOW - APPOINTMENT AND WALK-IN SYSTEMS

1. Walk-in patients with genital ulcers, discharges, and women with abdominal pain or who are pregnant are examined that day.

2. Patients referred by DIS are seen on a priority basis on the same day.

3. Walk-in patients who are not examined within the day are given a list of STD medical resources and eligibility requirements (e.g., urgent care clinics, family planning clinics, private physicians) and encouraged to call for a next-session appointment.

4. Patient stops are kept to a minimum (ideally, not more than three—registration, clinical care, and an STD/HIV interviewing/counseling session, if needed).

5. Patient flow analysis is conducted periodically to provide a systematic understanding of where bottlenecks in clinic flow occur.

6. .Appointment systems do not create barriers for clinic access.

F. MEDICAL RECORDS

1. Medical records contain sufficient demographic information to contact the patient and sufficient clinical evaluation information to readily interpret the examining clinician's assessment and clinical findings **(see chart audit for criteria)**.

2. STD programs follow written procedures for the management of medical records that includes forms management, organization of the medical record, records security, and adherence to statutes for record retention.

3. An individual is assigned the responsibility of managing the release of records due to subpoena, court order, etc. This person should track all matters relating to request to view medical records.

G. CLINIC MANAGEMENT STRUCTURE – Clinic Manager/Medical Director

1. The clinic manager has adequate specialized training in STD, clinic and personnel management, and public health to develop and implement clinic goals, policies, and procedures; manage personnel; orchestrate all clinic functions; and ensure quality of care.

2. The medical director has specialized training in STD, is available for consultation during clinic hours and ensures the overall quality of clinical services.

H. CLINIC MANUALS - Personnel Policies

1. Job descriptions and performance standards are provided for all staff members. These descriptions and standards should include:

   a. qualifications and training requirements for each job;
   b. the role each job plays in the operation of the clinic;
   c. a description of the essential tasks required for each job;
   d. the mechanism for performance evaluation; and,
   e. attitudes expected to be conveyed to clinic patients.

2. Policies regarding employee health (e.g., injury surveillance, HIV exposure, tuberculosis screening, and hepatitis B vaccination) are consistent with state and local employee health regulations and are clearly written and enforced.

3. Procedures for formal quality assurance are provided.

4. Written policies and procedures are in place to describe how the agency determines, documents, and reports instances of suspected child abuse in accordance with Chapter 261 of the Texas Family Code.

5. Written policies and procedures are in place to require documented training of all staff regarding every aspect of suspected sexual child abuse screening and reporting.

6. Written policies and procedures are in place to ensure reportable conditions are routed to the proper surveillance staff for reporting in accordance with TDH HIV/STD Surveillance Guidelines.

I. CLINIC MANUALS - Medical Protocols

1. There are approved clinic protocols (listing of steps to be taken to perform or deliver a clinical service) for specific patient management that include:

   a. patient evaluation;
   b. management of STDs (See CDC STD Treatment Guidelines);
   c. medical consultation and referral;
   d. follow-up after therapy;
   e. counseling/education;
   f. and management of sex partners.

2. Protocols include current recommended treatments for STDs.

3. Emergency medical protocols are current.

a. One copy of an emergency protocol is kept in the clinic manual and one copy with the emergency supplies.

b. Emergency equipment, supplies, and medications are updated frequently according to an established schedule to ensure that they are not depleted or expired. Emergency supplies are sealed when not in use.

4. Protocols for the safe handling of blood and body fluids (standard precautions) are current and practical for most clinic situations.

5. Standing delegation orders (written physician instructions designed for patient populations with specific diseases, disorders, health problems or sets of symptoms) are written, dated, and signed by the medical supervisor, and each registered nurse, licensed vocational nurse or any other staff members who function under these orders.

6. Procedures, protocols and standing delegation orders are current and updated periodically, but no less than annually.

J. CLINICIAN ROLES AND PERFORMANCE STANDARDS

1. Nurses, nurse practitioners, and physician assistants work in full compliance with established clinic protocols and standing delegation orders as clinicians responsible for the entire clinical care process, including history taking, physical examination, laboratory specimen collection, diagnosis, treatment, plan for follow-up, and counseling/education.

2. Non-physician clinicians have adequate physician backup and specific standing delegation orders signed by a physician.

3. Minimum background and training includes:

a. Licensure (i.e., licensed vocational nurse, registered nurse, nurse practitioner, physician assistant, or physician) or credentials required by the state or locality to perform the functions of an STD clinician. A process to verify current licensure is in place.

b. New clinicians who are developing skills receive a preceptorship before caring for patients under protocols and standing delegation orders.

c. All clinicians have had a specific STD training course (Comprehensive or Intensive STD Clinician Course at an STD Prevention/Training Center or a similar course) and AIDS update course that includes clinical and epidemiologic information about HIV infection within a year of employment.

d. Clinicians receive updates on STD and HIV topics at least every two years.

4. Clinicians perform the STD examination in the following manner (**see clinician audit form for criteria**):

   a. Clinicians present an image of sensitivity and competence to the patient.

   b. The medical history and the risk assessment is obtained by asking open-ended questions, e.g. how long, when, how many, what.

   c. Clinicians examined all appropriate anatomy with professional thoroughness.

   d. All laboratory specimens collected and labeled correctly.

   e. The examination, diagnosis, and treatment are accurate and noted in the medical record.

   f. Counseling messages are specific, clear, and brief, allowing time for patient's questions.

   g. Clinicians consult with the medical director on decisions that require a higher level of professional expertise.

   h. Clinicians strictly adhere to standard precautions (previously universal blood and body fluid precautions).

   i. Clinicians facilitate a seamless transfer of the case to other team members such as the DIS when appropriate.

   j. Clinicians inform the patient who will receive DIS services that another member of the health department staff will assist them. Making the introduction, or at least providing the name of the DIS, makes the transition more comfortable.

K. Laboratory Services

1. Each clinic that provides STD services has an on-site stat laboratory or capacity to perform stat tests. The laboratory must have a current CLIA certificate and be in compliance with CLIA-88.

2. At a minimum, stat laboratories should perform the following tests, all of which are classified as of moderate complexity under CLIA, with the exception of urine pregnancy tests, which are classified as waived under CLIA:

    a. gram stain to detect intracellular gram-negative diplococci and presence of white blood cells to detect cervicitis or urethritis
    b. nontreponemal antibody card tests for syphilis such as RPR, TRUST, RST
    c. darkfield examination for *Treponema pallidum*
    d. saline wet mount for *Trichomonas vaginalis* and detection of clue cells of bacterial vaginosis
    e. KOH wet mount for the identification of yeast and for amine odor (Whiff) test
    f. Urine pregnancy tests

3. Point-of-care tests are only used to provide immediate results and treatment to patients. If testing does not occur immediately, tests with greater sensitivity and specificity should be used.

L. QUALITY ASSURANCE PROCEDURES

1. A quality assurance committee meets regularly and follows an approved protocol to conduct audits, analyze findings, and deliver recommendations.

2. Medical records are audited regularly (checked against clinic protocols) to determine the appropriateness of diagnoses and treatment and the completeness of documentation.

3. The quality of stat laboratory procedures is monitored regularly.

4. Staff interactions with patients are observed regularly by appropriate clinical managers.

5. A mechanism has been established for receiving, reviewing, and responding to complaints of patients.

M. SEXUAL ASSAULT AND ABUSE

1. All clinic staff are familiar with provisions of the state child abuse and neglect statute and their obligations under it (Chapter 261 of the Texas Family Code).

2. Clinic staff members are familiar with applicable STD and HIV confidentiality statutes and are sensitive to any limitations on the reporting of supplementary information about suspected abuse cases.

3. The clinic manual specifies the management of patients of alleged abuse, listing the required examination and proper handling of laboratory specimens for evidence, and reporting procedures.

4. Testing of abused or assaulted patients is performed using the most specific tests available.

5. Clinics have set up a mechanism for referrals to perform additional confirmatory testing necessary to make a definite diagnosis.

6. Clinics have access to a patient advocate who maintains links with victim's assistance programs.

7. A completed checklist for screening for suspected sexual child abuse and reporting, in accordance with Chapter 261 of the Texas Family Code is evident in medical records when appropriate and contractually required.

STD CLINICAL SERVICES REVIEW

These standards are based on the 2001 CDC Program Operations Guidelines for STD Prevention, Medical and Laboratory Services; the essential functions contained in the Comprehensive STD Prevention Systems Program announcement; the 1991 CDC STD Clinical Practice Guidelines; and the 1997 TDH Client Services Standard for Public Health and Community clinics.

A standard is a consensus among STD clinic experts where the practice or technique is essential to effective and efficient program operation unless documentation from the particular setting shows otherwise.

M – Meets Standard
PM – Partially Meets Standard
NM – Does Not Meet Standard
NA – Not Applicable or Not Assessed

Clinic hours:
Clinicians:
Average daily patient load:
Number of patients turned away:

A. ACCESSIBILITY/CLINIC ENVIRONMENT

___1. The clinic facility is physically accessible in accordance with the Americans with Disabilities Act.

___2. The clinic is located so that it is readily accessible through public and private transportation from residential areas

___3. The general public can easily determine how to obtain specialized STD services.

___4. Clinic hours and staffing are sufficient to accommodate patients, with minimal patients turned away. (A minimum of 90% of clients seeking STD services will be seen the same day they seek services.)

___5. A system to document number of patients not seen "same day seeking services" is in place.

___6. A system to periodically assess clinic user (or patient) satisfaction with services is in place and information obtained is used to improve services.

___7. No patient is denied care for lack of money. Medical services should be at no charge, minimal, or based on a sliding scale.

___8. Fees are not assessed for examining persons referred by a disease intervention specialist.

___9. The building in which a STD clinic is located has signs making it easy to locate. Signs at the building entrance are easy to read and clearly list STD among the services.

___10. Waiting areas contain accessible patient education (i.e., handouts, posters, pamphlets, or audiovisuals), in languages appropriate to the populations being served that emphasize risk reduction behaviors for the prevention of STDs, HIV, and viral hepatitis.

___11. Examination rooms are clean and private and have adequate equipment and supplies for physical examinations and specimen collection for both male and female patients.

___12. The number of examination rooms is adequate to accommodate the number of clinicians (at least one room per clinician) and to serve patients promptly during the normal working day.

Significant Findings/Observations

Recommendations

B. RANGE OF SERVICES

___1. At a minimum, clinic has the capability to accurately diagnose and treat bacterial STDs (syphilis, gonorrhea, chlamydia, chancroid).

___2. Confidential counseling and testing for HIV are offered in accordance with *TDH HIV/STD Guidelines, Guidelines for HIV Testing in STD Clinics*, at the time of the STD visit so that patients do not have to visit separate clinics or make return visits.

___3. Clinic has the capacity to distribute medications for diseases diagnosed in the clinic. At a minimum, medications must be available for locally prevalent STDs, with prescriptions available for diagnosed diseases not prevalent in the community.

___4. Clinic provides condoms and counseling on primary prevention to all patients.

___5. If the clinic provides Pap smears, specific protocols for follow-up of abnormal results that include guidelines for colposcopy referral are in place and followed.

___6. If the clinic provides pregnancy tests, specific protocols for follow-up and referral of positive tests are in place and followed.

___7. Clinic collaborates with immunization programs and viral hepatitis programs to provide hepatitis B vaccinations to those at risk

___8. Clinic provides the basic range of HIV related services specified in state and federal statutes and, for patient convenience, offers as many as possible on site (e.g., counseling and testing, partner services).

___9. Confidential counseling and testing for STDs, including HIV, are not denied because a patient refuses other STD services.

___10. Anonymous HIV testing is available on site for patients requesting the service or at community sites convenient to patients. *TDH HIV/STD Guidelines, Guidelines for HIV Testing in STD Clinics* states that confidential testing is the preferred method.

___11. Written policy and procedures are in place for the referral of patients for HIV early intervention services (e.g., continuing medical evaluation, tuberculosis and immune system testing, treatment, penicillin desensitization, and support group counseling).

___12. When not offered on site, the mechanisms for referral are established for relevant health services (e.g., family planning, prenatal, adult immunizations, drug counseling) and a method to confirm appointments are kept is in place.

Significant Findings/Observations

Recommendations

C. PATIENT CONSIDERATIONS

___1. Patient confidentiality must be maintained. Confidentiality is promoted by using a system other than names when calling patients from waiting areas.

___2. Clinic personnel are courteous and respectful of patients.

___3. Patients are told what to expect during the clinic visit, including being told STDs for which they are being tested and the common ones for which they are not being tested.

___4. All clinic staff possess cross-cultural awareness and display cultural sensitivity to establish a positive clinic-patient relationship.

___5. An adequate portion of the clinic staff has bilingual fluency that facilitates services to those patients who do not speak English**.**

___6. An interpreter is available for deaf or hard of hearing patients.

___7. Clinic assesses the need for physical security during clinic sessions and has security protocols in place.

Significant Findings/Observations

Recommendations

D. REGISTRATION PROCESS – CONFIDENTIALITY & PROCEDURE

___1. Registration information is obtained in a confidential manner.

___2. Acoustical barriers separating clerks from waiting areas in addition to methods of self-registration are considered when distance does not prevent persons from overhearing those who are registering.

___3. Information collected at the registration desk is relevant: locating and demographic data, type of visit (referral, appointment, or walk-in); clerks should avoid discussing the medical reason for the visit including any symptoms or medical history.

___4. Patient address is verified at every visit in the event that follow up is needed.

___5. Positive HIV test results are not to be given over the telephone.

___6. Telephone reports of STD test results strictly follow clinic procedures to ensure confidentiality.

___7. Clinic has systems in place to assess and modify patient visits to assure minimal waiting.

___8. The "expected-in" file is checked for every person at every visit as part of the registration process. ("expected-in" is a record file of pending follow-up or priority examinations for disease intervention for the following: persons with reactive test results and untreated from the clinic or other facilities; sex partners or cluster suspects of diagnosed patients; and persons who need special repeat testing.)

___9. Priority (DIS referrals, follow-up visits) patients are given preferential service.

Significant Findings/Observations

Recommendations

E. CLINIC FLOW - APPOINTMENT AND WALK-IN SYSTEMS

___1. Walk-in patients with genital ulcers, discharges, and women with abdominal pain or who are pregnant are examined that day.

___2. Patients referred by DIS are seen on a priority basis on the same day.

___3. Walk-in patients who are not examined within the day are given a list of STD medical resources and eligibility requirements (e.g., urgent care clinics, family planning clinics, private physicians) and encouraged to call for a next-session appointment.

___4. Clinic flow is designed so that the next available clinician sees the next patient registered. An exception may be made where local medical practice standards or legislation stipulates gender requirements.

___5. Patients who request a clinician of a specific sex are accommodated whenever possible.

___6. Patient stops are kept to a minimum (ideally, not more than three—registration, clinical care, and an STD/HIV interviewing/counseling session, if needed).

___7. Patient flow analysis is conducted periodically to provide a systematic understanding of where bottlenecks in clinic flow occur.

____8. Appointment systems do not create barriers for clinic access.

Significant Findings/Observations

Recommendations

F. MEDICAL RECORDS

___1. Medical records contain sufficient demographic information to contact the patient and sufficient clinical evaluation information to readily interpret the examining clinician's assessment and clinical findings. (SEE CHART AUDIT FOR CRITERIA)

___2. All procedures concerning content and filing of medical records are in accordance with state and local laws and statutes.

___3. STD programs follow written procedures for the management of medical records that includes forms management, organization of the medical record, records security, and adherence to statutes for record retention.

___4. An individual is assigned the responsibility of managing the release of records due to subpoena, court order, etc. This person should track all matters relating to request to view medical records.

Significant Findings/Observations

Recommendations

CRITERIA FOR CHART AUDIT

Clinic:
Evaluator: **Date Evaluated:**
Clinic Manager: **Date Reviewed:**

STANDARD
NA = Not Applicable or Not Assessed
NI = Needs Improvement
S = Satisfactory

Chart I D						
REGISTRATION						
1. Name, address, telephone number						
2. Date of birth, race/ethnic origin, marital status, sex						
3. Emergency locating information						
MEDICAL HISTORY						
1. Reason for visit						
2. Description of symptoms (current symptoms, similar problems, or STD in sex partner)						
3. History of STD or HIV (treatment, dates)						
4. Review of medication hx (antibiotics, allergy, other)						
5. Review of blood donation, transfusion						
6. Review of blood tests for syphilis and for HIV (date and result)						
7. Review of general health						
8. History of drug use and needle-sharing						
9. Review of sexual activity (last exposure, number of partners, preference, exposure sites, condom use)						
10.**Women**-Reproductive hx (menses, contraception, pregnancy)						

SUMMARY OF FINDINGS:

Chart I D						
PHYSICAL EXAMINATION						
1. Inspection of skin (lesions, rashes, lymphadenopathy, discoloration)						
2. Inspection of oropharynx (lesions and discoloration)						
3. Palpation of inguinal, femoral, cervical, supraclavicular, epitrochlear, and axillary lymph nodes)						
4. **Genital – Women:** - Inspection of external genitalia (lice, nits, discharge, mass, lesions, tenderness) - Palpation of Bartholin's & Skene's glands - Inspection of cervix (discharge, ectopy, induced endocervical bleeding, lesions) - Inspection of vaginal mucosa (discharge, lesions) - Bimanual (cervical motion, adnexal tenderness, mass) - Inspection of anus and perianal area						
4. Genital – Men: - Inspection of pubic hair (nits, lice) - Inspection of penis, meatus, foreskin (discharge, lesions) - Palpation of scrotum (tenderness, mass) - Inspection of anus and perianal area						

SUMMARY OF FINDINGS:

Chart I D						
LABORATORY						
1. Appropriate specimens obtained - gram stain(GC, WBC) - gonorrhea test (s) (endocervical/urethral, oral, anal) - chlamydia test (endocervical, urethral) - STS (unless nonreactive in past 30 days) - HIV (unless nonreactive in past 30 days or positive in past) - **Women** – tests of vaginal discharge (wet mount, KOH)						
2. Additional tests from history and physical findings - Darkfield (lesions) - Other STD tests - Tuberculosis skin test/referral (if HIV positive) - Hepatitis B serologic test (e.g., HbsAG, anti-HBc) or vaccination - Hepatitis C serologic test - Pap smear or referral (if not done in past year) - Pregnancy test - STD tests during first and third trimester						
DIAGNOSIS						
Appropriate diagnosis made						
THERAPY						
Appropriate therapy provided in accordance with 2002 STD Treatment Guidelines or most current						

SUMMARY OF FINDINGS:

Chart I D						
COUNSELING/EDUCATION						
1. Partner notification & medical evaluation (disease transmission, complications, sex partner, treatment)						
2. Risk reduction messages (avoid sex until partners are examined, safer sex, reduce number of partners)						
3. Response to future disease suspicion						
4. Medication (name, schedule, side effects)						
5. Follow-up exam (procedures, consequences)						
6. patient handouts (disease- and treatment-specific)						
7. HIV risk-reduction messages (drug use, needle sharing, HIV testing, condoms, nitrite inhalants)						
CONSULTATION AND REFERRAL						
1. Appropriate referral to community resource and specialist						
2. Appropriate physician consulted						
FOLLOW-UP						
1. Medical history (symptoms, medications, sexual exposure, condom use)						
2. Physical exam						
3. Laboratory tests						
SIGNATURE						
Appropriate signature of clinician or others						
Consent forms signed and dated in record						

SUMMARY OF FINDINGS:

G. CLINIC MANAGEMENT STRUCTURE – Clinic Manager/Medical Director

___1. The clinic manager has adequate specialized training in STD, clinic and personnel management, and public health to develop and implement clinic goals, policies, and procedures; manage personnel; orchestrate all clinic functions; and ensure quality of care.

2. At a minimum, the job qualifications for clinic manager include:

___a. Adequate medical knowledge to make valid comparisons between observed clinician performance and clinic protocols

___b. Specialized STD training

___c. Clinic management training

___d. Public health experience or an orientation toward STD intervention concepts and activities to understand the needs of DIS supervisors and staff

___e. Understanding of standard laboratory procedures and methods to coordinate clinical and laboratory functions effectively

3. The clinic manager has the necessary training and authority to carry out various personnel management responsibilities relating to:

___a. Development of accurate job descriptions and reasonable performance standards for clinicians

___b. Providing staff orientation, familiarity with work plans, and knowledge of performance expectations

___c. Arranging for adequate staffing to care for the patient population (even when vacations are scheduled)

___d. Assuring staff training and updates in STD patient management and standard precautions (universal precautions).

4. The clinic manager ensures that:

___a. Clinic policies and procedures are developed, implemented and updated

___b. Information is communicated to all staff through regular staff meetings and that staff are encouraged to make suggestions about policies

___c. Clinic manual is current and accessible to all employees.

___d. All personnel observe standard (universal) blood and body fluid precautions

___e. Patient flow is optimal including developing policies for triage

___f. Quality assurance procedures for the clinical aspects are implemented and maintained

___g. The clinic facility, including equipment and supplies, is adequate for the patient population

___h. Appropriate medical oversight is available as needed

___i. Quality assurance functions related to clinic operations are performed at regular intervals and the results are used to modify operations manuals

___5. The medical director has specialized training in STD, is available for consultation during clinic hours and ensures the overall quality of clinical services.

6. The responsibilities of the medical director include:

___a. Signing standing delegation orders for non-physician clinicians and acting as the final authority on medical care in the clinic.

___b. Being in the clinic, being available, or arranging for physician coverage in the director's absence, for consultation with non-physician clinicians during all clinic hours.

___c. Assisting with the training of clinicians who need help to improve or upgrade their clinical practices.

___d. Assisting the clinic manager in clinician performance evaluations.

___e. Routine auditing (personally or by delegation) of all medical records to ensure that diagnoses are consistent with clinic protocols.

___f. Ensuring that the quality assurance committee's recommendations concerning medical care are implemented.

Significant Findings/Observations

Recommendations

H. CLINIC MANUALS - Personnel Policies

___1. An STD clinic manual should contain the goals and the objectives of the clinic, including fully integrated STD/HIV services.

2. Job descriptions and performance standards are provided for all staff members. These descriptions and standards should include:

___a. qualifications and training requirements for each job;
___b. the role each job plays in the operation of the clinic;
___c. a description of the essential tasks required for each job;
___d. the mechanism for performance evaluation; and,
___e. attitudes expected to be conveyed to clinic patients**.**

___3. Policies regarding employee health (e.g., injury surveillance, HIV exposure, tuberculosis screening, and hepatitis B vaccination) are consistent with state and local employee health regulations and are clearly written and enforced.

___4. Procedures for formal quality assurance are provided.

___5. Local policies and procedures included in the manual (frequency of staff meetings, fire drill instructions, sick leave, and vacation) are current.

___6. Written policies and procedures are in place to describe how the agency determines, documents, and reports instances of suspected child abuse in accordance with Chapter 261 of the Texas Family Code.

___7. Written policies and procedures are in place to require documented training of all staff regarding every aspect of suspected sexual child abuse screening and reporting.

___8. Written policies and procedures are in place to ensure reportable conditions are routed to the proper surveillance staff for reporting in accordance TDH HIV/STD Surveillance Guidelines.

Significant Findings/Observations

Recommendations

I. CLINIC MANUALS - Medical Protocols

1. There are approved clinic protocols (listing of steps to be taken to perform or deliver a clinical service) for specific patient management that include:

   ___a. patient evaluation;
   ___b. management of STDs (See CDC STD Treatment Guidelines);
   ___c. medical consultation and referral;
   ___d. follow-up after therapy;
   ___e. counseling/education;
   ___f. and management of sex partners.

___2. Protocols include current recommended treatments for STDs.

___3. Emergency medical protocols are current.

   ___a. One copy of an emergency protocol is kept in the clinic manual and one copy with the emergency supplies.

   ___b. Emergency equipment, supplies, and medications are updated frequently according to an established schedule to ensure that they are not depleted or expired. Emergency supplies are sealed when not in use.

___4. Protocols for the safe handling of blood and body fluids (standard precautions) are current and practical for most clinic situations.

___5. Standing delegation orders (written physician instructions designed for patient populations with specific diseases, disorders, health problems or sets of symptoms) are written, dated, and signed by the medical supervisor, and each registered nurse, licensed vocational nurse or any other staff members who function under these orders.

___6. Procedures, protocols and standing delegation orders are current and updated periodically, but no less than annually.

Significant Findings/Observations

Recommendations

J. CLINICIAN ROLES AND PERFORMANCE STANDARDS

___1. Nurses, nurse practitioners, and physician assistants work in full compliance with established clinic protocols and standing delegation orders as clinicians responsible for the entire clinical care process, including history taking, physical examination, laboratory specimen collection, diagnosis, treatment, plan for follow-up, and counseling/education.

___2. Non-physician clinicians have adequate physician backup and specific standing delegation orders signed by a physician.

___3. Minimum background and training includes:

___a. Current licensure (i.e., licensed vocational nurse, registered nurse, nurse practitioner, physician assistant, or physician) or credentials required by the state or locality to perform the functions of an STD clinician. A process to verify current licensure is in place.

___b. New clinicians who are developing skills receive a preceptorship before caring for patients under protocols and standing delegation orders.

___c. All clinicians have had a specific STD training course (Comprehensive or Intensive STD Clinician Course at an STD Prevention/Training Center or a similar course) and AIDS update course that includes clinical and epidemiologic information about HIV infection within a year of employment.

___d. Clinicians receive updates on STD and HIV topics at least every two years.

6. **OBSERVATION - Clinicians perform the STD examination in the following manner (SEE CLINICIAN AUDIT FORM FOR CRITERIA)**

___a. Clinicians present an image of sensitivity and competence to the patient.

___b. The medical history and the risk assessment is obtained by asking open-ended questions, e.g. how long, when, how many, what.

___c. Clinicians examined all appropriate anatomy with professional thoroughness.

___d. All laboratory specimens collected and labeled correctly.

___e. The examination, diagnosis, and treatment are accurate and noted in the medical record.

___f. Counseling messages are specific, clear, and brief, allowing time for patient's questions.

___g. Clinicians consult with the medical director on decisions that require a higher level of professional expertise.

___h. Clinicians strictly adhere to standard precautions (previously known as universal blood and body fluid precautions).

___i. Clinicians facilitate a seamless transfer of the case to other team members, such as the DIS, when appropriate.

___j. Clinicians inform the patient who will receive DIS services that another member of the health department staff will assist them. Making the introduction, or at least providing the name of the DIS, makes the transition more comfortable.

Significant Findings/Observations

Recommendations

CLINICIAN AUDIT FORM

Clinician: **Date Evaluated:**
Clinic:
Evaluator:

STANDARD
NI = Needs Improvement
S = Satisfactory
E = Excellent

INITIAL INTERACTION	**Pt 1**	**Pt 2**	**Pt 3**
Cordially greets patient by name			
Professionally introduces self and observer			
Establishes rapport with patient			
MEDICAL HISTORY	**Pt 1**	**Pt 2**	**Pt 3**
Uses open-ended questions to elicit information			
Ascertain the following:			
Reason(s) for visit			
Description of symptoms:			
Onset, duration, characteristics, frequency			
History of problems in a sex partner			
History of similar problems			
History of STD including HIV, treatments, dates			
Medication history:			
Recent antibiotic use (date, type, purpose, duration)			
Other medications (type, purpose, date, duration)			
Known drug allergy (drug, reaction, date)			
History of blood tests for syphilis and HIV (date, place, result)			
Review of general health:			
Time since last sexual exposure			
Number and change of partner(s) in last month			
Sexual preference(s)			
Exposure sites (oral, genital, anal)			
Sexual practices (STD risk assessment)			
Condom use			
Women - Reproductive history			
Date of last menses			
Unusual aspects of last menses (flow, duration, pain)			
Type of contraception (referral to family planning)			
Last/current pregnancy			

SUMMARY OF FINDINGS:

PHYSICAL EXAM	Pt 1	Pt 2	Pt 3
Follows infection control procedures to avoid cross-contamination			
Inspects face, trunk, forearms, palms, soles, for lesions, rashes, nodes, discoloration			
Inspects oropharynx for lesions and discoloration			
Palpates inguinal, femoral, cervical, supraclavicular, epitrochlear, and axillary lymph nodes			
Genital – Women			
Inspects external genitalia (discharge, masses, lesions, tenderness)			
Inspects the vaginal mucosa (discharge amount, color, character, lesions)			
Inspects the cervix (discharge amount, color, character, swab test)			
Notes presence of ectopy, induced endocervical bleeding, unusual findings			
Performs bimanual exam (cervical motion tenderness, uterine enlargement, adnexal tenderness, pelvic mass)			
Palpates Bartholin's and Skene's glands			
Inspects anus and perianal area			
Genital – Men			
Inspects pubic hair			
Inspects penis, meatus, foreskin (urethral discharge, color, amount, character, lesions)			
Palpates scrotum (testicular tenderness, mass)			
Inspects anus and perianal area			

SUMMARY OF FINDINGS:

LABORATORY SPECIMEN COLLECTION	Pt 1	Pt 2	Pt 3
Collects all specimens appropriately			
Gram stain (gonorrhea, WBC)			
Gonorrhea diagnostic test(s) (endocervical/urethral, anal or oral if exposure site, DGI)			
Chlamydia diagnostic test (endocervical/urethral)			
STS (unless nonreactive in last 30 days)			
HIV antibody test (initial visit, genital ulcer, exposure)			
Women – Tests of vaginal discharge:			
Wet mount (trichomonas and clue) KOH mount (yeast) Gram stain (trichomonas, yeast, clue) and pH			
Collects additional tests based on history and physical findings:			
Darkfield (chancre, rash, condylomata lata)			
STS (unexplained lesion, sex partner to case)			
Hepatitis B serologic test or vaccination			
Hepatitis C serologic test			
Correctly labels all specimens			
Collects and transports specimens correctly			
DIAGNOSIS AND TREATMENT			
Accurately determines and records diagnosis			
Selects appropriate treatment according to CDC 2002 STD Treatment Guidelines or most current version			
MEDICAL CONSULTATION AND REFERRAL			
Provides appropriate referral to community resource			
Consults appropriately with physician (unsatisfactory exam, diagnosis uncertain, drug reaction, no standing order)			
Refers to appropriate specialist (hospitalization, prenatal care, contraception, urologic and prostatic disorder, drug reaction, surgery)			

SUMMARY OF FINDINGS:

COUNSELING/EDUCATION	Pt 1	Pt 2	Pt 3
Clearly informs patient of diagnosis:			
Name of disease, transmission, incubation, s/s, etc.			
Complications			
Stresses partner notification :			
Refers to DIS for interview when indicated			
Provides written referral for partner to seek STD medical evaluation/treatment at this facility			
Refers partners to another medical facility for STD medical evaluation/treatment			
Gives risk-reduction messages			
Avoidance of sex with partners until examined			
Results and interpretation of tests			
Safe sex (abstinence, monogamy, condoms)			
Counsels on prevention of future infections (stop having sex, seek care promptly if symptoms recur)			
Gives accurate medication instructions			
Name of medication and why it is used			
How to take the medication and what to expect as treatment outcome			
Potential side effects			
Schedules follow-up exams			
Clinic procedure for follow-up exams			
Health consequences of not taking tests			
Recommends lifestyle/sexual activity changes until follow-up completed			
Provides patient handouts when appropriate (disease-specific, treatment-specific)			
Gives additional HIV risk-reduction messages			
Avoid injection drug use, sharing needles, unsterilized equipment			
Abstain from sex with persons suspected of HIV infection and other high risk individuals			
Seek HIV testing if future behavior puts one at risk for HIV			
Use latex condoms (multiple or new partners)			

SUMMARY OF FINDINGS:

CLINICIAN'S ATTITUDE	Pt 1	Pt 2	Pt 3
Invites patient to ask questions			
Answers patient questions appropriately			
Determines understanding of results/instructions			
Remain sensitive to patients concerns			
Maintains a relaxed manner throughout the interaction			
Maintains a nonjudgmental attitude			
EMERGENCY PRECAUTIONS			
Appropriate use of emergency protocol			
Emergency medications administered correctly			
FOLLOW-UP THERAPY			
Ascertains follow-up history			
Changes in symptoms			
Adverse reaction to drugs			
Compliance with instructions			
Sexual exposure since therapy			
Treatment status of sex partner(s)			
Collects appropriate laboratory tests			
BIOSAFETY PROCEDURES			
Follows biosafety and infection control protocol			

SUMMARY OF FINDINGS:

K. LABORATORY SERVICES

___1. Each clinic that provides STD services has an on-site stat laboratory or capacity to perform stat tests. The laboratory must have a current CLIA certificate and be in compliance with CLIA-88 **(see Appendix ML-A of CDC Program Operations Guide, Medical and Laboratory Services).**

___2. At a minimum, stat laboratories should perform the following tests, all of which are classified as of moderate complexity under CLIA, with the exception of urine pregnancy tests, which are classified as waived under CLIA:

___a. Gram stain to detect intracellular gram-negative diplococci and presence of white blood cells to detect cervicitis or urethritis
___b. nontreponemal antibody card tests for syphilis such as RPR, TRUST, RST
___c. darkfield examination for *Treponema pallidum*
___d. saline wet mount for *Trichomonas vaginalis* and detection of clue cells of bacterial vaginosis
___e. KOH wet mount for the identification of yeast and for amine odor (Whiff) test
___f. Urine pregnancy tests

___3. Point-of-care tests are only used to provide immediate results and treatment to patients. If testing does not occur immediately, tests with greater sensitivity and specificity should be used**.**

___4. The stat laboratory contains an appropriate number of brightfield and darkfield microscopes and adequate equipment, supplies, and reagents to process patient specimens rapidly.

___5. A sufficient number of staff are trained in darkfield microscopy to provide coverage during all clinic hours where rapid syphilis diagnosis is desirable.

___6. The stat laboratory sends the following routine tests to the state health laboratory or other nonstat laboratory:

___a. presumptive and confirmatory identification and antimicrobial sensitivity tests for *N. gonorrhoeae; [presumptive-moderate complexity; confirmatory and sensitivity tests-high complexity-CLIA]*
___b. chlamydia diagnostic tests (most high complexity - CLIA)
___c. nontreponemal antibody tests for syphilis (VDRL - high complexity, RPR and other similar card tests - moderate complexity - CLIA **)**
___d. fluorescent treponemal antibody absorption (FTA-ABS) or other treponemal tests for syphilis [high complexity-CLIA]; and
___e. HIV antibody tests [moderate complexity-CLIA, many others, high complexity-CLIA]

___7. Additional stat testing may include;

___a. Tzanck stain for herpes [moderate-CLIA]
___b. spun urine for Gram stain and white cell count [moderate-CLIA]

___8. STD clinics use routine and reference laboratory services that further facilitate the diagnosis of STDs.

Significant Findings/Observations

Recommendations

L. QUALITY ASSURANCE PROCEDURES

___1. A quality assurance committee meets regularly and follows an approved protocol to conduct audits, analyze findings, and deliver recommendations.

___2. Medical records are audited regularly (checked against clinic protocols) to determine the appropriateness of diagnoses and treatment and the completeness of documentation.

___3. The quality of stat laboratory procedures is monitored regularly.

___4. Staff interactions with patients are observed regularly by appropriate clinical managers.

___5. Semiannual safety audits are performed to determine the appropriate use of electrical equipment, storage of chemicals, emergency procedures, and first-aid stations.

___6. A mechanism has been established for receiving, reviewing, and responding to complaints of patients.

___7. Representatives of the finance office and data processing unit are included on the quality assurance committee so that they can gain and maintain an understanding of clinic operational needs.

Significant Findings/Observations

Recommendations

M. SEXUAL ASSAULT AND ABUSE

___1. All clinic staff are familiar with provisions of the state child abuse and neglect statute and their obligations under it (Chapter 261 of the Texas Family Code).

___2. Clinic staff members are familiar with applicable STD and HIV confidentiality statutes and are sensitive to any limitations on the reporting of supplementary information about suspected abuse cases.

___3. The clinic manual specifies the management of patients of alleged abuse, listing the required examination and proper handling of laboratory specimens for evidence, and reporting procedures.

___4. Testing of abused or assaulted patients is performed using the most specific tests available.

___5. Clinics have set up a mechanism for referrals to perform additional confirmatory testing necessary to make a definite diagnosis.

___6. Clinics have access to a patient advocate who maintains links with victim's assistance programs.

___7. A completed checklist for screening for suspected sexual child abuse and reporting, in accordance with Chapter 261 of the Texas Family Code is evident in medical records when appropriate and contractually required.

Significant Findings/Observations

Recommendations